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| 09/806,989 | 05/29/2001 | Wilfred Wayne Lutt | 2495.00071 | 7861 |

7590 04/27/2005

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| EXAMINER |
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DELACROIX MUIRHEI CYBILLE

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,989

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Cybille Delacroix-Muirheid

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 19 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-3 and 19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/01/2004.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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Detailed Action

1. Claims 1-3 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an NO donor compound such as SIN-1, SNAP, sodium nitrite and nitroprusside does not reasonably provide enablement for all types of compounds which fall within the scope of "nitric oxide donors".

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Since new claim 19 is dependent on claim 1, it is also rejection under 35 USC 112, first paragraph for reasons given previously in the office action mailed Sep. 22, 2004 as well as for the reasons presented below.

Response to Amendment(s)

The following is responsive to applicant's amendment received Jan. 21, 2005.

Claims 4-18 are cancelled. New claim 19 is added. Claims 1-3, 19 are currently pending.

Applicant's information disclosure statement received Nov. 1, 2004 has been considered. Please refer to applicant's copy of the 1449 submitted herewith.

The previous claim objection set forth in paragraph 1 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

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The previous claim rejection under 35 USC 112 second paragraph, set forth in paragraph 3 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejection under 35 USC 102(b) set forth in paragraph 4 of the office action mailed Sep. 22, 2004 is withdrawn in view of applicant's amendment and the remarks contained therein.

However, applicant's arguments traversing the previous claim rejection under 35 USC 112, first paragraph, set forth in paragraph 2 of the office action mailed Sep. 22, 2004 have been carefully considered but are not found to be persuasive in so far as the arguments relate to the portion of the scope of enablement rejection addressing the limitation "nitric oxide donors." The portion of the scope of enablement rejection relating to the general "administration" of the compounds is withdrawn in view of applicant's amendment and the remarks contained therein.

Said rejection is maintained essentially for the reasons given previously in the office action mailed Sep. 22, 2004 with the following additional comment.

Applicant states that the claims, as amended, recite the administration of nitric oxide (NO) donors. The specification teaches that insulin sensitivity is increased in the liver by administering a compound that stimulates NO production in the liver and shows that insulin resistance is reversed by administering an NO donor directly to the liver. Applicant contends that NO donor compounds are well known in the art and their function is predictable, and the level of skill in the art is high. Therefore, in view of the teachings in the specification and level of skill in the art, one of ordinary skill in the art

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would reasonably expect any compound that is a NO donor to be useful in the claimed method. One of ordinary skill in the art would be able to practice the claimed method without undue experimentation.

Said arguments have been considered but are not found to be persuasive.

According to the MPEP 2164.08, as concerns the breadth of a claim relevant to enablement, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. > AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244, 68 USPQ2d 1280, 1287 (Fed. Cir. 2003);< In re Moore, 439 F.2d 1232, 1236, 169 USPQ 236, 239 (CCPA 1971). See also Plant Genetic Sys., N.V. v. DeKalb Genetics Corp., 315 F.3d 1335, 1339, 65 USPQ2d 1452, 1455 (Fed. Cir. 2003). Furthermore, the scope of the claims must reasonably correlate to the scope of enablement provided by the specification to one of ordinary skill in the art. Please see In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

In this case, the Examiner respectfully submits that the scope of enablement in the disclosure does not bear a "reasonable correlation" to the scope of the claims. As discussed in the office action mailed Sep. 22, 2004, NO donor is a broad term, which encompasses a vast number of compounds with NO donor activity. In re Dreshfield, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled in cases involving chemicals and chemical compounds, which differ radically in their properties, it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals

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or chemical combination included in the claims are capable of accomplishing the desired result." Moreover, the court has held "cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Please see In re Fisher, 166 USPQ 18, 24 (CCPA 1970).

The Examiner respectfully submits that the scope of enablement provided to one of ordinary skill in the art by Applicant's disclosure is not commensurate with the scope of protection sought by Applicant's claims. The specification provides data evidencing the efficacy of only one compound (SIN-1) in reversing insulin resistance, yet the claims allow for the administration of vast number of NO donor compounds ranging from peptides to nucleotides to non-peptide organic compounds (e.g.heterocyclics). Therefore, the examiner respectfully maintains that one of ordinary skill in the art would be burdened with undue experimentation to practice the full scope of the claimed method.

Therefore, the rejection is respectfully maintained.

Conclusion

Claims 1-3, 19 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

CDM

April 25, 2005


RAYMOND HENLEY III
PRIMARY EXAMINER
AU 1614